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IN THE

Supreme Court of the United States

October Term, 1963

No. 536

An article of drug consisting of 47 bottles, more or less, each containing 30 capsules of an article labeled in part: "• • • JENASOL RJ FORMULA '60' • • • " ROYAL JELLY, etc.

MARVIN SCHERE, d/b/a JENASOL CO.,

Petitioner,

AGAINST

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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Petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Third Circuit, entered in the above entitled case on July 16, 1963.

Citations to Opinions Below

The opinions of the District Court are printed in Appendix A, *infra*, pages 11 and 24, and are officially reported at 200 F. Supp. 1 (1961) and 201 F. Supp. 915 (1962).

The opinion of the Court of Appeals is printed in Appendix A, *infra*, page 30, and is officially reported at 320 F. 2d 564 (1963).

Jurisdiction

The judgment of the Court of Appeals was entered on July 16, 1963 (Appendix A, *infra*, page 48). The jurisdiction of this Court is invoked under 28 U. S. C. 1254(1).

Questions Presented

1. Whether this Court's decision in *United States* v. *Urbuteit*, 336 U. S. 804 (1949), is to be changed so as to construe the statutory definition of "labeling" under the Federal Food, Drug and Cosmetic Act to mean literature which was intended for use, but which in fact was never used in the sale or offer for sale of the product.

2. Whether a finding of falsity, as a fact, can be made upon the testimony of respondent's own witnesses that the scientific questions have been neither proven nor disproven and are presently the subject of a difference of scientific opinion.

Statutes Involved

The statutory provisions involved are Sections 201(m), 201(n), 304 and 502(a) of the Federal Food, Drug and Cosmetic Act [21 U. S. C. 321(m), 321(n), 334 and 352(a)]. They are printed in Appendix B, *infra*, page 50.

Statement

The instant *in rem* action was commenced by the seizure of a number of bottles of a product known as Jenasol RJ Formula '60' Capsules (herein referred to as Jenasol Capsules) under the purported authority of 21 U. S. C. Section 334 (Federal Food, Drug and Cosmetic Act, Section 304). The libel of information alleges that the product was misbranded under 21 U. S. C. Section 352(a) in that the alleged labeling for the product falsely represented the therapeutic effectiveness of the product for various conditions and symptoms.

The articles seized consist of 23 bottles of Jenasol Capsules which were shipped by the petitioner to the company's own agent and field representative on July 7, 1958. The literature, here in issue, consists of folders and leaflets which were shipped on May 15, 1958 by the petitioner to its agent who stored same in his bedroom closet. The 23 bottles of the product were received by the company's agent and similarly were placed in his bedroom closet where they were found at the time that they were seized. The bottles and literature were not sent pursuant to any specific order, but were delivered for possible future use.

It is conceded that the literature was designed for use in the sale and distribution of this kind of product, but there was no evidence that any of the literature or leaflets had actually been used with respect to the sale or offer for sale of the 23 seized bottles or of any other units of the product. The respondent contended that said literature constitutes "labeling" for the seized 23 bottles of the petitioner's product and that various claims contained in said literature were false or misleading.

The District Court held that the articles were misbranded under 21 U. S. C. Section 352(a), on the ground

that the claims set forth in the literature were false or misleading in some particulars, and that the printed material constitutes labeling for the seized articles within the meaning of 21 U. S. C. Section 321(m).

The Court of Appeals affirmed the judgment of the District Court, except as to that portion of the judgment which provided for injunctive relief. The Court of Appeals held that the literature constitutes labeling under the Statute and interpreted this Court's ruling in *United States* v. *Urbuteit*, 336 U. S. 804 (1949), and 335 U. S. 355 (1948), to mean that this Court was not really promulgating two requirements in order for literature to constitute labeling for an article, when this Court stated that the controlling factors were whether the leaflets were designed for use and whether they were so used. In effect, the Court of Appeals held that compliance with only one of these requirements, to wit, that the literature was designed for use, is adequate to constitute the literature as labeling under the statute for the specific articles seized.

The Court of Appeals further affirmed the ruling of the District Court that various claims were false. This ruling was made in face of the fact that the respondent's own witnesses testified that the scientific questions presented had been neither proven nor disproven at this time and that there was a difference of scientific opinion relative thereto. The Court of Appeals apparently failed to rule upon the real issue presented in that it held that the Trial Judge made a choice between conflicting medical opinions. The issue herein presented was not a choice between conflicting medical opinions presented by the two parties, but rather a question as to whether a finding of falsity, as a fact, can be made where the record admittedly establishes that the scientific questions have not yet become crystalized into facts, but rather remain in the realm of disputed opinion.

Reasons for Granting the Writ

1. Petitioner respectfully submits that an important question of statutory construction is herein presented. The Court of Appeals handed down a ruling which interprets a decision of the United States Supreme Court in a manner which is at variance with the statements actually made by this Court in *United States* v. *Urbuteit*, *supra*.

The term "labeling" is a statutory word of art which is employed in numerous sections throughout the Federal Food, Drug and Cosmetic Act. Interpretations of this term have been handed down in a number of lower court decisions which have involved issues as to the meaning of this court's decisions in *United States* v. *Urbuteit*, *supra*, and *Kordel* v. *United States*, 335 U. S. 345 (1948). The decision of the Court of Appeals herein, has created further uncertainty and possible confusion. It is respectfully submitted that the uncertain state which presently exists relative to this question of statutory construction should be resolved and clarified.

The statutory term "labeling" is defined in Section 201(m) of the Federal Food, Drug and Cosmetic Act [21 U. S. C. 321(m)] as follows:

> "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

Concededly the literature herein does not fall within the first definition of labeling, of appearing upon the article or any of the its containers or wrappers. The issue involves an interpretation of the word "accompanying" as that word is used in the second definition of labeling.

In *United States* v. *Urbuteit*, 336 U. S. 804 (1949), this Court set forth the elements involved in the interpretation of the word "accompany", when it stated at page 805 of its decision:

> "The controlling factors were whether the leaflets were designed for use with the machine and whether they were so used."

See also, *Kordel* v. *United States*, *supra*, at page 350.

It would appear that this Court laid down two factors to be considered in determining whether literature "accompanies" an article so as to constitute labeling for said article. The Court of Appeals, however, has ruled that this Court was merely commenting upon the fact that the literature had in fact been used, but did not intend to thereby promulgate a requirement that there be an actual use in order for the literature to constitute labeling under the Statute.

The Court of Appeals has, therefore, ruled that there are not two factors, but only one which need be considered, and that one, merely that literature is designed for use with a product.

Significantly, it is the first element laid down by this Court, in *United States* v. *Urbuteit*, *supra*, which involves the question of intent or purpose. The functional connection or purpose is established as a separate and distinct factor from that of actual use. It is submitted that this Court added a second essential factor that, in addition to the purpose or intention for which the literature was designed to be used, *there must be actual use itself*. To hold otherwise would create a meaningless interpretation and definition of the statutory word "accompany" as set

forth by Congress in the Federal Food, Drug and Cosmetic Act.

One of the problems which flows from the ruling of the Court of Appeals, would be to determine precisely when literature becomes labeling for a specific article. If a state of mind or intent is adequate to make a piece of literature labeling for a specific article, then we would have to next consider the entire life history of the literature and of the article to attempt to determine when the literature *accompanies* the article under the Statute. We can begin with the very birth of these 23 bottles in the laboratory, while the circulars were sitting in a carton in the agent's bedroom closet from May 15, 1958. We can trace the life of the capsules during June and July as they travel from the laboratory to the petitioner and then on to the petitioner's agent when he placed the units in his bedroom closet. Exactly when, during this life cycle of the 23 bottles, can it be stated that the legal "accompaniment" occurred

It is respectfully submitted that no such "accompaniment", use or attachment ever occurred. There is nothing which has occurred at any time which could make the circulars sitting in the bedroom closet labeling for the 23 bottles which have been seized herein, and which constitute the *res* of this *in rem* proceeding.

This question is sharply delineated in the instant action for the very reason that it is an *in rem* proceeding wherein the specific units seized are alleged to have been misbranded when introduced into interstate commerce by reason of claims in its labeling material.

The petitioner does not contend that there need be a simultaneous shipment of the product and the circular material, nor need there be a physical attachment between

the circulars and the product. The petitioner does contend, however, that the literature must be designed for use with the product and that there must be some actual use of the literature with the product. The fact that literature may be designed for use, or intended for use, does not necessarily mean that there may ever arise an actual use so as to constitute an "accompanying" of the literature with the product under the Statute.

2. The Court of Appeals has further held that a finding of fact, as to falsity of a scientific claim, can be made by a Trial Judge under circumstances wherein the scientific question has not yet become crystalized into scientific fact, but is rather still in an area of opinion and difference of opinion among scientific experts. Cf. *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94 (1902).

It is not certain from a reading of the Court of Appeal's opinion whether the issue has really been met by that Court. Thus on page 12 of its opinion, the Court state:

> "In the case at bar, the Trial Judge made a choice between conflicting medical opinions."

That, however, is not precisely the issue presented by the petitioner herein.

Petitioner respectfully submits that the real issue is whether, as a matter of law, a finding of falsity as a fact, can be made where the record establishes that the scientific question has been neither proven nor disproven and is the subject of a difference of scientific opinion.

This is not a case where a number of experts testify for one party and a number of experts testify for the other,

and the Trial Court may choose to accept the experts of one party rather than the other. For the purpose of the issue herein presented, we can completely disregard the testimony of the experts who testified on behalf of the petitioner. We need merely consider the testimony of those experts who testified for the respondent. It is the respondent's own witnesses who testified that the questions as to efficacy had not been proven nor disproven and were in a state of a difference of opinion. The issue, therefore, is whether falsity of claims, as a fact, can be found under such circumstances.

This question is basic to all legal proceedings wherein scientific questions are in issue. It is not a question of the burden of proof as to preponderance of evidence, substantial evidence, or proof beyond a reasonable doubt. Rather, it is an overriding issue which was considered by this Court, to some extent, in the case of *American School of Magnetic Healing v. McAnnulty, supra.*

It has been recognized that scientific questions go through various stages. They begin as theories and proceed through the crucible of experience and testing to attain the status of crystalized facts. It is submitted that a court of law cannot make a finding of truth or falsity with respect to a scientific question which is at a stage where it has not as yet been resolved by experience and testing into a fact, but is in that period of its development wherein it is a question of opinion and difference of opinion in the scientific community.

Petitioner respectfully submits that these questions should be resolved and that settlement thereof is in the public interest.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

MILTON A. BASS,
SOLOMON H. FRIEND,
Counsel for Petitioner.

Dated: October 4th, 1963.

APPENDIX A

OPINION

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

Civil Action No. 1042—58

UNITED STATES OF AMERICA,

Libellant,

vs.

An article of drug consisting of 47 bottles, more or less, each containing 30 capsules of an article labeled in part: "* * * JENASOL RJ FORMULA '60' * * *"

Respondent,

(MARVIN SCHERE d/b/a the JENASOL CO.),

Claimant

APPEARANCES:

DAVID M. SATZ, JR., ESQ., United States Attorney. By: JEROME D. SCHWITZER, ESQ., Assistant United States Attorney

and

WILLIAM GOODRICH, ESQ., General Counsel Department of Health, Education & Welfare, Food and Drug Administration (D. C. Bar). By WILLIAM R. RISTEAU, ESQ. (Illinois Bar) For the Government.

BASS & FRIEND, ESQS. By MILTON BASS, ESQ. (New York Bar) Attorneys for Claimant.

WORTENDYKE, District Judge:

This is a seizure case under the Federal Food, Drug and Cosmetic Act, 21 U. S. C. §301 et seq. The subject matter of the seizure is a quantity of drug labelled "Jenasol RJ Formula 60"[2] capsules or "Jenasol" containing as active ingredients a substance designated as "Royal Jelly"[1] and certain vitamins.[2]

The libel of information charges misbranding within the meaning of 21 U. S. C. §352(a), because labelling claims as to the therapeutic effectiveness of the drug are false and misleading. It is represented in the labelling that the product will cause a person who ingests it to obtain increased sexual vitality, relief from irritability, headaches, insomnia, physical and spiritual convulsions, and depression, restoration of vitality, alleviation of the ills of old age, improvement of memory, stimulation of appetite, normalization of the growth of under-developed

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[1] 5 Encyl. Brit. 11th Ed. 628 (Titles Bee) "It is believed that from the nature of the cell in which she is ovipositing, the queen derives a reflex impulse to lay the appropriate egg—fertilized in the queen or worker cell, unfertilized in the drone cell. * * * Whether the fertilized egg shall develop into a queen or a worker depends upon the nature of the food. All young grubs are at first fed with a specially nutritious food, discharged from the worker's stomach, to which is added a digestive secretion derived from special salivary glands in the worker's head. If this 'royal jelly' continue to be given to the grub throughout its life it will grow into a queen; if the ordinary mixture of honey and digested pollen be substituted, as is usually the case from the fourth day, the grub will become a worker."

[2] The label upon the container of the drug states: "Each capsule contains: Thiamine Hydrochloride (Vit. B-1) 10 mgm. 1000% MDR Riboflavin (Vit. B-2) 5 mgm. 250% MDR. Pyridoxine Hydrochloride (Vit. B-6) 1 mgm. Ascorbic Acid (Vit. C) 50 mgm. 166% MDR Vit. B-12 (Activity Equivalent) 5 mcg. Folic Acid 0.2 mgm., Niacinamide 50 mgm. Calcium Pantothenate 2 mgm Royal Jelly (need in human nutrition not established) 50 mgm In a natural base of wheat germ oil (Vit. E)."

children, extension of life-span, palliation of glandular activation, alleviation of the physical and mental symptoms of approaching old age, help for tired eyes, and the achievement of a pleasing state of relaxed well-being.

In addition to the issue of fact posed by the charge that the claims are false and misleading, two questions of law are raised, namely: (1) whether the printed matter seized with the article of drug constitutes labelling within the meaning of 21 U. S. C. §321(m), and (2) whether the evidence disclosed a substantial difference of medical opinion with respect to the claims upon which the issue of fact arises. Having charged misbranding, the burden rests upon the Government to support the accusation by competent evidence. *Chichester Chemical Co. v. United States*, D. C. Cir. 1931, 48 F. 2d 516. In undertaking to discharge this burden the Government called nine expert witnesses, whose identity, qualifications and opinions were as hereinafter summarized.

Howard Smith, a chemist in the field of food analysis, conducted a "regular" food analysis on pure royal jelly for the purpose of determining the percentages of protein, sugars, acid and ash contained therein; and found that the ingredients of the royal jelly aggregated a total of 100.7%.

Dr. Paul Gyorgy, specializing in nutrition and pediatrics the discoverer of certain vitamins and an author and professor in his fields, testified, on the basis of knowledge of royal jelly, derived from scientific literature dealing therewith, that Jenasol would have none of the effects claimed in its labelling, except in cases of loss of appetite resulting from insufficiency of the thiamin vitamin. He was further of the opinion, based upon his studies and professional contacts, that there was no basis for believ-

ing that royal jelly is useful in the treatment of any disease.

Dr. Herbert S. Kupperman, Associate Professor of Medicine, specializing in the fields of endocrinology and clinical pharmacology, had made a study prior to the institution of the present litigation for the purpose of determining the effects of ingested royal jelly upon the human body with particular reference to the endocrine glands, the libido, and the gonadal function of the human male. His study involved the administration of royal jelly to a number of rats, and a comparison of its effect, with that of an inert substance, upon the weights of the adrenals, testes, prostate, seminal vesicles, levator ani muscles, thymus, thyroid and pituitary glands of the animals. Finding that the weight of these organs was not affected by the administration of the substance, Dr. Kupperman concluded that royal jelly had no hormonal or other effect on the male sex organs. It was, moreover, his opinion that the results obtained from the administration of the substance to the rats would be similar in the case of human beings. Supplementing his tests upon rats, he administered the product to several healthy males. He observed no effect of the tests, except the development of diarrhea in the patients. In a second test on human beings, the Doctor administered the royal jelly to seven patients who suffered from problems relating to fertility and libido, with glandular deficiencies. By measuring the quantity of steroid substances, an index of the activity of the male sex organs, in the blood and urine of the patients, and comparing the findings with those present prior to the administration of the royal jelly, no significant differences were manifested. Dr. Kupperman concluded from these tests that none of the patients had experienced any enhancement of libido, increase in sperm count, or change in sterility. His findings that the sub-

stance administered did not enhance potency was based upon information given him by the patients. In sum, it was the opinion of Dr. Kupperman that the Jenasol formula would not be effective in the treatment of the diseases and conditions for which it was recommended in its promotional literature, and that his opinion thereon represented the informed medical consensus upon the subject.

Another witness for the Government was Dr. Lewis Barness, an Associate Professor Pediatrics and board-certified specialist therein, who had conducted research in nutritional pediatrics. It was his opinion that royal jelly was not a recognized treatment for underdeveloped children. He had administered Jenasol to six underdeveloped children for thirty days, and noted no improvement, and he testified that he would not prescribe the Jenasol formula for such patients because it did not contain vitamins A or D. Throughout his participation in meetings of physicians and other scientists, and his connection with medical schools, Dr. Barness had never heard any discussion regarding royal jelly.

Dr. William H. Lewis, a medical professor presently associated with the Sloan-Kettering Medical Center, and an author of articles and books dealing with diseases connected with the aging process, voiced the opinion that the Jenasol product, except as a B-vitamin supplement when necessary, was ineffective for the geriatric diseases, and that royal jelly was not recognized as a treatment for them. The substance had been tested at the institution with which he was connected as a possible cancer remedy, and found to be ineffective for that purpose as well.

Dr. Ernest J. Umberger, a pharmacologist employed by the Food and Drug Administration, specializing in the

study of glands, had administered royal jelly to rats. He found through two tests that the animals to which royal jelly had been given did not react any differently than did the control, and concluded, therefore, that royal jelly did not stimulate the ovaries or adrenal glands at which the tests were directed. In a third study, this doctor administered royal jelly and a control to castrated male rats in an effort to determine the presence of male sex hormonal activity and growth stimulant effects, if any. He found no such activity as a result of the administration of the substance, and concluded, as the result of several tests, that royal jelly contained no substance stimulative of the adrenal gland, and also that it had no toxic effect.

Another expert witness who testified in behalf of the Government was Dr. Arthur Grollman, who had been teaching medicine at Johns Hopkins University and at the University of Texas over a period of thirty-eight years. He is a prolific writer on medical subjects and the recipient of numerous academic honors and fellowships, including an honorary professorship of medicine at the University of Guadalajara, Mexico. He has studied and written upon the subject of royal jelly, which he recognizes as a plentiful source of pantothenic acid. It was his considered opinion that the Jenasol product would not be effective in the treatment of any of the conditions mentioned in its labelling, except in cases of certain well-defined vitamin deficiencies. Dr. Grollman also confirmed Dr. Umberger's opinion that the results of the tests which the latter made upon rats were significant of similar effects upon human beings. Dr. Grollman stated that the antibiotic activity of royal jelly was but a negligible fraction of that afforded by the usual dosage of bacitracin, streptomycin, polymixin, neomycin and penicillin. The doctor also stated that he knew of no

medical school in which the use of royal jelly as a therapeutic agent was taught, and that his opinion represented the consensus of medical opinion on the subject.

The case of the Government concluded with the testimony of Mr. Bernard Arrett, an employee of the Division of Antibiotics of the Food and Drug Administration. He had made certain tests to determine the effect of royal jelly in Jenasol as inhibitors of bacterial growth. From these experiments he found that the antibiotic activities of the substances lay in the range attributable to such foods as honey, sugar, butter, milk, green peppers, foods having a high salt content, and cranberries.

The evidence adduced in behalf of the claimant was in the form of testimony by Dr. Angel Lozano Abarca, a thirty-three year old Mexican physician with a background of only five years' practice, and Dr. Ricardo Galeazzi-Lisi, formerly a physician to the Pope, who admitted that he was neither a scientist nor a researcher, and had kept no records of his clinical use of royal jelly.

Dr. Abarca testified that he had employed royal jelly principally for the treatment of physical impotency in men with favorable results in 80% of the cases treated. He explained the absence of response in the remaining 20% by the presence of diabetes in those unresponsive cases. The doctor was, however, of the opinion that royal jelly was effective in the treatment of diabetes, and testified that he had used it for that purpose. He also stated that he had used the substance in the treatment of some accompaniments of old age, including arthritis, with apparently resultant improvement. His admitted source of knowledge respecting the composition and effects of royal jelly was, however, information which he obtained from a veterinarian, Hector Lopez Arista, who was engaged in the business of distributing royal

Jelly in Mexico City, and who had worked out for Dr. Abarca the dosages to be used. The witness conceded that he had no knowledge of any recommendations for the use of the substance in medical textbooks, or in medical schools, and his opinion as to its efficacy for the purposes stated in the labelling was based only on his own work, and the "study" of the veterinarian, whose testimony was not presented.

Dr. Galeazzi-Lisi initially claimed that he had administered royal jelly to "many thousands" of persons since he first learned of it in 1947 or 1948; but later in his testimony the doctor reduced his estimate of the number of subjects from thousands to hundreds. He testified that he used the drug primarily in efforts toward the retardation of the aging process and in the treatment of the symptoms associated with old age; also, but to a lesser extent, as a means of increasing the weight of underdeveloped children. He claimed to have achieved favorable results in these directions. He was unable to afford any specific information concerning the food value or protein content of royal jelly, or to name any one of the forty ingredients of which he claimed it was composed. He testified further that he was currently experimenting with royal jelly in the treatment of cancer. He reiterated his disclaimer of any scientific or research qualifications in that field.

The article seized in this case consisted of 23 bottles of a substance called "Jenasol RJ Formula 60" which was shipped by the claimant Jenasol Company from New York City on July 7, 1958, to O. E. Haugland, Route 2, Milton, Washington, a field representative, salesman and agent for the shipper in the State of Washington. 438 copies of written, printed and graphic matter, shipped by the claimant to the same consignee on May 15, 1958, were also seized. These consisted of a folder entitled

"Miracle Bullets" a leaflet entitled "Jenasol Co." and a reorder leaflet entitled "This is Our Unconditional Guarantee". Also seized were 306 copies of a leaflet entitled "Royal Jelly Passport to Health", printed locally by Haugland in Milton, Washington, from a "mat" supplied to him by the Jenasol Company. The 438 copies of the written, printed and graphic matter above referred to were shipped in a single carton, removed therefrom by the consignee, and assembled into sets consisting of one copy of each of the three foregoing categories, stapled together. Haugland would deliver a "set" of this literature with each bottle of Jenasol capsules sold and delivered to a customer. He also distributed such "sets" to prospective customers as sales inducements. The bottles of Jenasol capsules seized had not been ordered by Haugland to comply with any specific request from a customer, but only in his capacity as field representative and agent for Jenasol, as part of his stock to be thereafter sold. Prior to the time of seizure, the capsules and literature seized were being stored by Haugland in his bedroom closet for future sales purposes.

The Court was furnished with a translation into English of what purport to be excerpts from the proceedings of the first international conference for the study of bees' products in the medico-biological field, at Bologna, Italy, in 1956, entitled "Observations on Feeding of Prematures with Royal Jelly." The discussion suggests that the effect of royal jelly upon the queen bee justifies the assumption that the same substance may be usefully employed in the nutrition of premature human babies. From a review of nine specific cases treated with the substance, the conclusion is drawn that the use of royal jelly as an integrative of the ailment for immature babies promises satisfactory results.

The claimant attacks the testimony of the witnesses for the Government upon the grounds that they lack sufficient basis for expert knowledge, and have not received adequate instruction in the medical field. Claimant further impugns the competency of those witnesses by reason of their ignorance of all component ingredients of royal jelly, and the inconclusiveness of their experiments (except those of Dr. Kupperman). It is claimant's contention that libelant has failed to discharge its burden of proof that royal jelly is not therapeutically effective for the conditions claimed in the labeling, and that the evidence discloses that there exists a conflict of scientific opinion as to the efficacy of the substance for the purposes enumerated.

Claimant affirmatively asserts that its witnesses are the only qualified experts upon the critical issue, and that their opinions, which rest upon clinical observations, are conclusive of the therapeutic efficacy of royal jelly for the conditions claimed in the labeling.

It is the efficacy of the royal jelly component in the Jenasol formula which is the bone of contention in this case. Indeed, it is the unknown constituent in royal jelly which is relied upon by the claimant as the efficient cause of the therapeutic benefits recited in the labeling. Claimant's contention respecting the beneficence of royal jelly is a deduction from an assumption that because the queen bee thrives upon the substance, while the other members of the hive, without it, fail to enjoy her vigor and longevity, its administration to human beings must be productive of comparable results. There has been no showing in the evidence in this case that a human being is likely to react to the ingestion of royal jelly in any manner, direction or degree similar to the reaction of the queen bee to the inclusion of such a substance in her diet. If, as the claimant contends, the results of

the administration of royal jelly to rats are irrelevant to the effects of the substance upon human beings, the effects of the substance upon the queen bee are certainly not to be compared to those which may be expected in the case of human babies or old people. Recognizing, however, that the burden of proof of inefficacy is imposed upon the Government in this case, we look to the net effect of the evidence proffered in support of its contention as compared with that offered by the claimant. The latter argues that because no one has succeeded in completely analyzing the composition of royal jelly, it cannot be said that it lacks a component which might be efficacious in the treatment of the conditions set forth in the labeling. The Government contends, however, that reliable medical opinion negatives the efficacy of the substance for some, if not for all of the objects set forth in the labeling.

The statute, 21 U. S. C. 352(a) defines as misbranding a drug whose labeling is false or misleading in *any* particular and renders the drug liable to seizure if it is misbranded. Labeling, as used in the statute means "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article." 21 U. S. C. 321(m). In order to justify the present seizure, the Government is required to show by the preponderance of the evidence that the labeling of the drug is false or misleading in some particular. No fraudulent intent on the part of the claimant need be shown as is required to sustain a fraud order of the Postmaster General. *American School of Magnetic Healing* v. *McAnnulty*, 1902, 187 U. S. 94. See also *Reilly* v. *Pinkus*, 1949, 338 U. S. 269. To sustain its burden of proof in the present case, the Government must show by the greater weight of the believable evidence that the Jenasol labeling is false or misleading in some particular. *United States* v. *Kaadt*, 7 Cir. 1948, 171 F. 2d 600.

I conclude from the substantial evidence which has been produced before me in this case that the Government has sustained its burden of proof. Whether a consensus of medical opinion exists respecting the effectiveness of the seized drug for the purposes claimed in the labeling, and whether there is a conflict in the medical opinion in that regard, are issues of fact which I am called upon to resolve in the case. *Seven cases* v. *United States*, 1916, 239 U. S. 510; *United States* v. *Kaadt*, *supra*; *United States* v. *Dr. David Roberts Veterinary Co.*, 7 Cir. 1939, 104 F. 2d 785. The substantiality of the evidence inducive of my conclusion finds support in the criteria enunciated in venerable authority. 3 Wigmore, Evidence 687 at 3 (3d Ed. 1940); *United States* v. *Wood*, 4 Cir. 1955, 226 F. 2d 924; *Irwin* v. *Federal Trade Commission*, 8 Cir. 1944, 143 F. 2d 316; *John J. Fulton Co.* v. *Federal Trade Commission*, 9 Cir. 1942, 130 F. 2d 85, cert. den. 1942, 317 U. S. 679; *Neff* v. *Federal Trade Commission*, 4 Cir. 1941, 117 F. 2d 495.

That the printed material in which the alleged false and misleading representations were set forth constitutes labeling within the meaning of the Act is obvious, because that material, together with the drug itself, constitutes "parts of an integrated distribution program" as disclosed on the face of the material and in the stipulated facts. *Kordel* v. *United States*, 1948, 335 U. S. 345, 350; *United States* v. *Urbuteit*, 1948, 335 U. S. 355; *United States* v. *353 Cases* * * * *Mountain Valley Mineral Water*, 8 Cir. 1957, 247 F. 2d 473; *United States* v. *4 Devices* * * * *Color-Therm*, 10 Cir. 1949, 176 F. 2d 652; *United States* v. *10 Cartons* * * * *Black Tablets*, D. C. Pa. 1957, 152 F. Supp. 360.

To discharge its burden of proof under the statute, the government was required to adduce substantial evidence tending to show that the labeling was "false or

(note disjunctive) misleading in any particular." 21 U. S. C. §352(a); *United States* v. *Hoxsey Cancer Clinic*, 5 Cir. 1952, 198 F. 2d 273, cert. den. 1952, 344 U. S. 928; *United States* v *Six Dozen Bottles* * * * *Dr. Peter's Kuriko*, 7 Cir. 1947, 158 F. 2d 667; *Goodwin* v. *United States*, 6 Cir. 1924, 2 F. 2d 200. The ample evidence to be found in the testimony of the witnesses for libelant that the drug was not an effective agent in the treatment of headaches, tired eyes, spiritual or physical convulsions was not even contradicted by claimant, who did not even explain what was meant by "spiritual convulsions" as used in the labeling.

Despite the ostensible relation of the representations in the labeling to the synergistic effect of all the ingredients of the Jenasol capsule, a careful reading of the printed matter in conjunction with a fair interpretation of claimant's evidence leads one to the inevitable conclusion that it is the royal jelly in the formula which renders the drug efficacious for the represented purposes. Although in its circular entitled "Miracle Bullets", claimant states that it makes no claims for Royal Jelly, all of claimant's evidence related only to the efficacy of royal jelly in the fields of pediatrics and gerontology. In any event, the labeling, when read as a whole is, at best, misleading. *United States* v. *38 Dozen Bottles* * * * *Trypsin*, D. C. Minn. 1953, 114 F. Supp. 461.

A decree of condemnation will be entered against the articles seized in this case, which shall direct the destruction thereof, and for the award of costs to libelant against the claimant. This opinion shall constitute the findings of fact and conclusions of law required by F. R. C. P. 52(a).

REYNIER J. WORTENDYKE, JR.
Judge, United States District Court

OPINION

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

Civil Action, No. 1042—58

UNITED STATES OF AMERICA,

Libellant,

vs.

An Article of Drug consisting of 47 bottles, more or less, each containing 30 capsules of an article labeled in part: "* * * JENASOL RJ FORMULA '60' * * * "

Respondent

APPEARANCES:

DAVID M. SATZ, JR., ESQ., United States Attorney, by JEROME D. SCHWITZER, ESQ., Assistant United States Attorney

and

WILLIAM GOODRICH, ESQ., General Counsel Department of Health, Education & Welfare, Food and Drug Administration (D. C. Bar) By WILLIAM R. RISTEAU, ESQ. (Illinois Bar) For the Government.

BASS & FRIEND, ESQS., (New York Bar) By MILTON BASS, ESQ. Attorneys for respondent.

WORTENDYKE, District Judge:

In its opinion, filed December 14, 1961, this Court found that Jenasol capsules, an article of drug, seized under 21 U. S. C. §301, et seq., was misbranded because the claims set forth in its labelling were false and misleading.

On December 18, 1961 respondent obtained an order to show cause why the entry of judgment should not be stayed pending clarification of the Court's findings of fact; clarifying said findings of fact; permitting relabelling of the articles seized; and staying the execution of the decree of condemnation pending an appeal from said decree of condemnation.

The Government now moves to amend the prayers for relief in the libel to include an injunction to prevent the sale of respondent product. Such a form of relief is authorized by 21 U. S. C. 332(a).

The issues presented on return of the order to show cause were orally argued on January 22, 1962, and decision reserved thereon, excepting the application for a stay of entry of judgment, which was denied. (The judgment order when submitted should provide for a stay of destruction of the product under condemnation, pending appeal, if taken within time.)

The motion to clarify and expand the Court's opinion was not opposed by the Government, for the apparent reason that the Food and Drug Administration, now seeking an injunction, recognizes the necessity of specific findings with regard to each of the alleged false representations in the labelling in order to render enforceable the injunctive relief which it seeks. Whether or not an injunction could properly issue barring the future sale of Jenasol RJ Formula "60" capsules with each of the representations presently contained in the labelling thereof

without more specific findings of fact, was not argued by the parties. However, it was impliedly conceded by the Government that an injunction against the labelling *in toto* might be too broad in scope in view of the findings already made.

The Court has found that a decree of condemnation should issue upon "the ample evidence to be found in the testimony of the witnesses for libellant that the drug was not an effective agent in the treatment of headaches, tired eyes, spiritual or physical convulsions" which evidence "was not even contradicted by claimant." It was not incumbent upon the Court to specifically "find" with regard to each and every allegation of misbranding contained in the libel, but in view of the present applications, explicit findings will be made as to the efficacy of Jenasol R.J Formula "60" Capsules as an adequate and effective treatment for: —increasing sexual vitality, irritability, insomnia, depression, restoring vitality, alleviating ills of old age, improving memory, stimulating the appetite, normalizing growth of underdeveloped children, extending the span of human life, digestive disturbances, activating glands of the body, physical and mental symptoms of approaching old age; and whether it is a "natural supertonic" which produces a pleasing state of well being.

The promotional literature accompanying the article of drug in this case holds out the hope to the public that any of the above-mentioned conditions may be effectively remedied by the ingestion of Jenasol R.J Formula "60" Capsules because they contain "miracle" royal jelly. In addition to this ingredient, the capsule is said to contain numerous vitamins in a natural base of wheat germ oil. The evidence adduced establishes that the vitamins contained in the pills may be efficacious in treating some of the disabilities listed.

Dr. Gyorgy, a Government witness, conceded that loss of appetite caused by insufficiency of the Thiamin vitamin might respond to treatment with the product with which we are here concerned. However, such occasions are very rare, and occur only when the condition complained of is a result of a vitamin deficiency. In such cases the effective agent is not the royal jelly but the vitamins contained in the product, and it is clear from reading the literature advertising the capsule that it is not being marketed as a vitamin compound but as a miraculous panacea for the ills described, by reason of its inclusion of the ingredient described in bold print as "Royal Jelly". The promotional literature must be read as a whole. *38 Dozen Bottles * * * Trutacin*, 114 F. Supp. 461. It is upon the royal jelly that sufferers from the conditions stated are induced by the literature to pin their hopes and fasten their expectations of alleviation and restoration. When read as a whole, the labelling creates and is intended to create the impression upon the sufferer of the stated ills that it is the royal jelly ingredient of the capsule which constitutes the efficacious palliative or therapeutic agent. I find this to be false, and the labelling as a whole consequently misleading. In view of this unmistakable implication of the labelling, the conclusion is inescapable that the labelling is false and misleading in all respects. The specific findings upon which the Court relied in determining royal jelly to be ineffective for the purposes stated in its labelling are set forth in its opinion filed December 14, 1961. The testimony of the witnesses presented by the Government amply supports the libellant's burden of proof.

The remaining question to be resolved is whether libellant's proposed amendment to the libel, to include a prayer for injunctive relief, should be granted. No case has been found on point, i.e., where a plenary trial was held and

decision rendered prior to the application to amend the prayer to include additional and novel relief. However, under the general principles of law, there does not appear to be a prohibition against granting such additional relief.

In *Zig Zag Spring Co.* v. *Comfort Spring Co.*, 3 Cir. 1953, 200 F. 2d 901, the Court upheld District (now Circuit) Judge Smith who, upon completion of the trial allowed the plaintiff to amend its complaint to include "and maliciously" thus entitling it to punitive damages, where the case was tried upon that theory, or at least that element was stressed during the trial, and no surprise pleaded or request for continuance made.

The dispositive question is whether or not the opposing party has been prejudiced. Even in cases where the amendment involves a change of the legal theory or cause of action, such changes have been allowed in the absence of a showing of prejudice.

Thus there appears to be no adequate reason to preclude the Government from obtaining the additional relief it now seeks where the legal theory upon which the case was tried would justify the injunction sought, in addition to a decree of condemnation.

There has been no showing that the illegal conduct complained of has ceased. In fact, upon oral argument, it was conceded that sales of the condemned product are continuing with similar labelling. They are likely to continue unless enjoined.

An injunction may be granted even after the illegal conduct has ceased. See *United States* v. *W. T. Grant Co.*, 345 U. S. 629, 633.

The prayers of the libel will be deemed amended to include one for an injunction against further sales of the condemned product with any of the labelling here found to be false and misleading. The injunction so sought is hereby granted.

An order in conformity with the foregoing shall be submitted.

REYNIER J. WORTENDYKE, JR.
Judge, United States District Court.

OPINION OF THE COURT
(Filed July 16, 1963)

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 14035

UNITED STATES OF AMERICA,

v.

An Article of Drug Consisting of 47 Bottles, More or Less, Each Containing 30 Capsules of an Article Labeled in Part "* * * JENASOL RJ FORMULA '60' * * *"

MARVIN SCHERE, Doing Business as the JENASOL COMPANY, Appellant

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APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Argued March 5, 1963

Before BIGGS, *Chief Judge*, and KALODNER and FORMAN, *Circuit Judges*.

By BIGGS, *Chief Judge*.

This is an appeal from an order of the court below entered February 21, 1962, directing the condemnation of a drug and enjoining the claimant, Marvin Schere, doing

business as Jenasol Company (Jenasol), from re-introducing the drug into interstate commerce as labeled or as accompanied with certain labeling materials. The case arises under the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. 301 *et seq.*

On May 15, 1958, approximately 438 copies of promotional leaflets for a drug known as "Jenasol RJ Formula '60' Capsules" were shipped by Jenasol from New York City to the home of O. E. Haughland, a Jenasol representative and sales agent in Milton, Washington.[1]

On July 7, 1958, 23 bottles each containing 30 capsules of the drug itself, "Jenasol RJ Formula '60' ", were shipped from New York by Jenasol to Haughland's home in Washington. Haughland stored both the previously shipped leaflets and the capsules themselves in his bedroom closet and kept the items there as stock for future sales. The leaflets, broken by Haughland into sets consisting of one copy of each of three different circulars and stapled together, were to be distributed to each customer purchasing the drug and also were to be used for advertising and promotional purposes.

The drug, "Jenasol RJ Formula '60' Capsules", contains as its featured ingredient a substance known as "royal jelly", which, simply described, is the special food fed by worker bees to a newly hatched bee destined to become a queen. The drug contains certain well-known

[1] 47 bottles of the drug were shipped by Jenasol to Haughland on the same day, May 15, 1958, but were returned and shipped back to Jenasol by the agent shortly thereafter. See the stipulation of the parties.

vitamins and minerals in addition to "royal jelly".[2] The promotional leaflets shipped by Jenasol to its agent in the State of Washington for use with the capsules represent to the public that the drug would alleviate mental depression, loss of appetite, sexual weakness, nervousness, and several other ailments, and that it would increase "pep, energy and sexual drive".

Pursuant to an alias warrant of seizure and monition issued by the United States District Court for the Western District of Washington on August 7, 1958, the United States Marshal for that District seized 23 bottles of Jenasol capsules[3] and several hundred sets of the promotional literature[4] from the possession of Haughland, the Jenasol agent. The seizure was based on a libel of information filed by the United States which alleged that the capsules were misbranded in interstate commerce within the meaning of 21 U. S. C. A. 352(a) in that the promotional literature accompanying the capsules constituted false and

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[2] The label on the 30-capsule bottle of "Jenasol RJ Formula '60' Capsules" contains the following statement of ingredients: "Each capsule contains: Thiamine Hydrochloride (Vit. B-1) 10 mgm. 1000% MDR, Riboflavin (Vit. B-2) 5 mgm. 250% MDR, Pyridoxine Hydrochloride (Vit. B-6 ‡) 1 mgm. Ascorbic Acid (Vit. C) 50 mgm. 100% MDR, Vit. B-12 (Activity Equivalent ‡) 3 mcg., Folic Acid ‡ 0.2 mgm., Niacinamide ‡ 30 mgm., Calcium Pantothenate * 2 mgm. ROYAL JELLY * 50 mgm. In a natural base of wheat germ oil (Vit. E)." The various symbols are indicated as follows: "MDR—Minimum Daily Requirement"; "‡ Need established MDR not established."; "* Need in human nutrition not established."

[3] The libel and monition designated the res as 47 bottles of Jenasol capsules. Both parties stipulated, however, that these 47 bottles had been shipped back to Jenasol in New York prior to seizure, and that the seized res, consisting of 23 bottles, had been shipped by Jenasol to Haughland on July 7, 1958. See note 9, *supra*.

[4] Some of the literature had been printed in the State of Washington from a mat supplied by Jenasol in New York and sent to Haughland for that purpose.

misleading labeling. The relief prayed for in the libel was that the court decree the condemnation of the article.

Jenasol Company intervened as claimant, and, pursuant to an order of the United States District Court for the Western District of Washington dated September 8, 1958, the case was transferred to the United States District Court for the District of New Jersey[2] where trial was had before Judge Reynier J. Wortendyke, Jr.

In its opinion, filed on December 14, 1961,[3] the court found as a fact that the literature was false and misleading as to the efficacy of the drug, concluded that the literature constituted "labeling" within the meaning of 21 U. S. C. A. §321(m), and stated that a decree of condemnation would be issued.[4] Entry and issuance of the decree was stayed on motion by the claimant for clarification of findings of fact, pursuant to Fed. R. Civ. P. 52(b), 28 U. S. C. Shortly after the stay, the United States moved to amend the libel to include a prayer for injunctive relief against the claimant. In a second opinion, filed February 6, 1962,[5] the court specially found that the labeling was false and misleading in all respects, deemed the libel amended to include a prayer for injunctive relief in accordance with the motion of the United States, and granted the injunc-

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[2] The transfer was made pursuant to 21 U. S. C. A. §334(a), which provides in pertinent part: "... [T]he proceeding pending or instituted shall, on application of the claimant ... be removed for trial to any district agreed upon by stipulation between the parties or, in case of failure to so stipulate ... the court of the district in which the seizure has been made ... shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business ..."

[3] United States v. 47 Bottles, More or Less, Jenasol RJ Formula, 201 F. Supp. 1 (1961).

[4] 201 F. Supp. 915 (1962).

tion against Jenasol. An order of condemnation and injunction against the claimant was issued on February 21, 1962.[8] The appeal to this court followed.

Jenasol's first contention is that the leaflets seized with the drug do not constitute labeling within the meaning of the Federal Food, Drug and Cosmetic Act. Section 321(m), Title 21, U. S. C. A. provides: "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." It is clear from the stipulated facts that the material alleged to be labeling was not physically attached to the drug or its package. Determination of this issue, then, depends upon the construction to be given the statutory phrase "accompanying such article". We must, of course, have in mind the intent of Congress in enacting the Federal Food, Drug and Cosmetic Act. In United States v. Dotterweich, 320 U. S. 277, 280 (1943), it was said "The purposes of this legislation . . . touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely

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[8] The decree appealed from, in addition to ordering the condemnation of the res, enjoins the claimant "From introducing or delivering for introduction or causing to be introduced or delivered for introduction into interstate commerce any article of drug known as 'Jenasol RJ Formula 360' Capsules, or the same drug by any other name, or any similar article of drug, which is accompanied by any written, printed, or graphic matter which represents or suggests that the said article is an adequate and effective treatment for increasing sexual vitality, irritability, headaches, insomnia, physical and spiritual convulsions, depressions, restoring vitality, alleviating ills of old age, improving memory, stimulating the appetite, normalizing growth of underdeveloped children, extending span of human life, digestive disturbances, activating glands of the body, physical and mental symptoms of approaching old age, tired eyes, and that the article is a 'Natural supertonic' which 'produces a pleasing state of relaxed well-being,' or any similar statements, which statements are false and misleading within the meaning of 21 U. S. C. §352(a) since the article is not adequate and effective treatment for such conditions and purposes."

beyond self protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words." [9]

The written material alleged to be labeling was, as we have stated, shipped by Jenasol from New York to Haughland in Milton, Washington on May 15, 1958, and the 23 bottles of the drug were shipped on July 7, 1958. The leaflets and the drugs were stored by Haughland in his bedroom closet, unquestionably with the intent to use the leaflets with the drug for sales and promotional purposes. There is no evidence, however, that the leaflets were actually used in either respect.

The definitive test of whether literature can be said to accompany an article and thus constitute labeling within the meaning of the Act was set forth in Kordel v. United States, 335 U. S. 345, 350 (1948): "One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment of one to the other is necessary. It is the textual relationship that is significant." The textual relationship and supplemental

[9] See United States v. 7 Jugs, Etc. of Dr Salsbury's Rakos, 58 F. Supp. 740, 752-53 (D. Minn. 1944): "... [O]f paramount importance is the fact that the Federal Food, Drug and Cosmetic Act is an enactment under the Commerce Clause. . . . One of the most important enactments under the Commerce Clause, its purpose of protecting the public health and pocketbook against adulterated and misbranded food and drugs, has led courts to declare, with unanimity that food and drug legislation should be given a liberal construction in order to accomplish its remedial purposes.

* * * * *

"Realizing that Congress was attempting to expand the protection given consumers in redefining the concept of misbranding, it is evident that the word 'accompany' should be given an interpretation which accords with the Congressional purpose.

nature of the literature in the appeal at bar, the leaflets entitled "Miracle Bullets", "Jenasol Co.", "This is Our Unconditional Guarantee", and "Royal Jelly Passport to Health",[10] is made obvious by a reading of these materials. Each explains the uses of the royal jelly product and the purported health benefits to be derived from it. It is clear then, that these materials together with the drug constitute parts of an "integrated distribution program". Kordel v. United States, *supra* at p. 350; United States v. Lee, 131 F. 2d 464 (7 Cir. 1942).[11]

It is true that the literature and the drugs shipped from Jenasol in New York to its agent in the State of Washington were sent on different dates and in different packages. This, however, does not alter the status of the literature as labeling, for there need not be physical accompaniment of the literature and the drugs to which they relate during the interstate journey. Kordel v. United States, *supra*. In V. E. Irons, Inc. v. United States, 244 F. 2d 34, 39 (1 Cir. 1957), certiorari denied, 354 U. S. 923 (1957), the Court stated: "It is clear that the term 'labeling' must be given a broad meaning to include all literature used in the sale of food and drugs, whether or not it is shipped into interstate commerce along with the article." See also United States v. Urbuteit, 335 U. S. 355, 357-358 (1948). In United States v. 7 Jugs, Etc., Dr. Salsbury's Rakos, 53 F. Supp. 746, 755 (D. Minn. 1944), the Court said: ". . . [T]he printed

[10] The latter leaflet, entitled "Royal Jelly Passport to Health", was printed by Haughland in Washington from a mat supplied by Jenasol in New York.

[11] That the literature in the case at bar might be said to be advertising material is of no moment, for advertising can and, in the instant case, does serve the function of labeling. See Kordel v. United States, 335 U. S. 345 (1948); United States v. Urbuteit, 335 U. S. 355 (1948).

matter and the drugs had a common origin. They had a common destination in that both were intended to come together. . . . They were interlocking units of a distributional scheme the objective of which was ultimate association and distribution together. . . . [T]hese booklets were prepared, shipped and distributed to dealers with the ultimate expectation and intention . . . that they would serve the purpose of labeling for the . . . articles . . . here involved. Without the booklets, the products themselves lacked labeling, at least in so far as informing purchasers of the purposes and uses of the remedies. The mere fact that the products were shipped at a different time, over a different route, and were received at a different time from the booklets should not be permitted to confuse or obscure the substance of the matter" [12]

Jenasol insists, however, that for literature to be said to have accompanied a drug within the meaning of the Act there must have been actual use of the literature as labeling, and, it points out that the record is barren of any evidence of such actual use. United States v. Urbuteit, 336 U. S. 504 (1949), and Kordel v. United States, 335 U. S. 345 (1948), are cited in support of this position. In both cases, the Supreme Court referred to an actual use of the literature. A careful reading of the opinions, however, reveals that the Supreme Court was commenting on the fact that the literature had in fact been used as labeling. Due consideration was given to this factor of use by the Court,

[12] In United States v. Research Laboratories, 126 F. 2d 42, 45 (9 Cir. 1942), the court stated: "... [It is not material], whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their inter-state journey. The packages and the circulars had a common origin and a common destination. . . . Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey."

but it cannot be said that in doing this the Court promulgated or intended to promulgate a requirement that there be an actual use in order that the literature constitute labeling. Moreover, in United States v. 353 Cases * * * Mountain Valley Mineral Water, 247 F. 2d 473, 478 (8 Cir. 1957), the same argument raised by Jenasol in the appeal at bar was asserted, and rejected by the court. The claimant urged that leaflets could not properly be deemed to be labeling "because of evidence that they had not been used by the distributor in connection with selling the [mineral] water. . . . However, all of the pamphlets were obviously printed for use generally in promoting the sale of the water, and were useful for no other purpose. All of them were found in the place of business of the local distributor. . . . ." The Court concluded, *supra* at p. 480, that "all of the sales literature . . . was, as a matter of law, 'labeling'. . . ." The facts on the issue of use in United States v. 353 Cases, *supra*, are virtually identical with those in the instant appeal on the same question. See also United States v. 10 Cartons * * * Black Tablets, 152 F. Supp. 360 (W. D. Pa. 1957); United States v. 4 Devices * * * Color-Therm, 176 F. 2d 652 (10 Cir. 1949). But see Lee v. United States, 187 F. 2d 1005 (10 Cir. 1951).[13]

We are of the opinion, in the light of the authorities cited or quoted, that the court below decided correctly

[13] See United States v. Lee, 151 F. 2d 464, 466 (7 Cir. 1942): "There can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates, and that the basic character of the Federal Food, Drug and Cosmetic Act is not directly concerned with the sale of the products therein described, or whether the literature is carried away by the purchaser. It was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction. Consequently, we are compelled to the conclusion that misbranding is cognizable under the Act while the articles are being held for sale."

that the literature in the case at bar constituted labeling within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. §301 *et seq.*

Jenasol next contends that the trial court erred in denying its motion to dismiss the libel of information for want of legally sufficient allegations of fact to support the assertion that the literature constituted labeling. We think that the district court was correct in denying this motion and that, therefore, Jenasol's contention is without merit. Paragraph II of the amended libel, that of August 7, 1958, alleges the shipment in interstate commerce of the leaflets by title, of the mat from which Haughland was to print, and from which he did print, another titled leaflet, and of the drugs. Paragraph IV alleges that the drug was misbranded "when introduced into, while in and while held for sale after shipment in interstate commerce" in that the leaflets, functioning as labelling, were false and misleading in the representations they made concerning the efficacy of the drug as treatment for specifically designated ailments. It is clear that the facts alleged in the libel show a "functional interdependence" between the promotional literature claimed to be labeling and the drug to which the literature refers, and the libel is, therefore, legally sufficient in this respect. See United States v. 8 Cartons [illegible] Molasses, 97 F. Supp. 313, 315 (W. D. N. Y. 1951).

We now turn to a consideration on the merits of the claim of misbranding. A brief review of the pertinent statutory provisions is necessary.

Section 331, Title 21, U. S. C. A., the provision containing the basic prohibition of the Federal Food, Drug and Cosmetic Act, provides: "The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of

any food, drug, device, or cosmetic that is adulterated or misbranded." Section 352, Title 21, U. S. C. A., states that "A drug or device shall be deemed to be misbranded —(a) If its labeling is false or misleading in any particular."

Section 321(n), Title 21, U. S. C. A., provides: "If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."

Statutory authority for the issuance of a decree of condemnation by the district courts is found in 21 U. S. C. A. §334(a), which provides in pertinent part: "Any article of food, drug, device, or cosmetic that is . . . misbranded when introduced into or while in interstate commerce while held for sale . . . after shipment in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel information and condemned . . ." Broad authority for the issuance of an injunction is found in 21 U. S. C. A. §332(a) (1962 Supp.): "The district courts of the United States . . . shall have jurisdiction, for cause shown, . . . to restrain violations of section 331 of this title. . . ."

The United States was required to bear the burden of proof at trial in order to establish that the labeling was

false or misleading. Calusa Remedy Co. v. United States, 176 F. 2d 554, 556 (8 Cir. 1949). To meet this burden, the testimony of nine expert and highly qualified witnesses was presented. These witnesses included in their numbers a research chemist specializing in food analysis, a specialist in nutrition, an endocrinologist, a pediatrician, a specialist in the field of geriatrics, and a pharamacologist. The testimony of these witnesses was based primarily upon controlled scientific and clinical tests performed by them or under their supervision and upon evaluations of the consensus of medical opinion. As to this latter evidence, see Research Laboratories, Inc. v. United States, 167 F. 2d 410, 416 (9 Cir. 1948). See also 3 Wigmore, Evidence 687 at p. 3 (3d Edition).

To rebut the Government's case, the claimant presented the testimony of two expert witnesses, Drs. Angel Lozano Abarca and Ricardo Galeazzi-Lisi. Dr. Abarca, a young Mexican physician in practice for five years, based his conclusions as to efficacy of royal jelly on clinical experience with the substance, although he admitted that his knowledge of the composition and proper dosages of royal jelly was based on information given him by a veterinarian engaged in the distribution of royal jelly in Mexico City. Dr. Galeazzi-Lisi, a personal physician to the late Pope Pius XII, based his testimony as to the efficacy of the royal jelly on clinical experience also. However, he disclaimed any scientific or research qualifications, and apparently had kept no clinical records or controls.

The court below, after weighing the evidence, found that the United States had met its burden of proof and that royal jelly was not an effective treatment or palliative for human ailments as was claimed in the labeling. The court did find, however, that the evidence established that

the vitamins contained in the capsules "may be" an effective treatment for some of the ailments enumerated in the labeling. Nonetheless, the court concluded that: "When read as a whole, the labeling creates and is intended to create the impression upon the sufferer of the stated ills that it is the royal jelly ingredient of the capsule which constitutes the efficacious palliative or therapeutic agent. I find this to be false, and the labeling as a whole consequently misleading. In view of this unmistakable implication of the labeling, the conclusion is inescapable that the labeling is false and misleading in all respects." United States v. 47 Bottles . . Jenasol RJ Formula '60', 201 F. Supp. 915, 917 (D. N. J. 1962).

Our review on appeal of findings of fact made by a district court is, of course, far from a plenary one. Rule 52(a), Fed. R. Civ. P., 28 U. S. C. A., provides in part that "Findings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses." Whether or not labeling is false or misleading in any particular is a question of fact for determination by the trial judge in the absence of a jury. Colusa Remedy Co. v. United States, 176 F. 2d 554, 561 (8 Cir. 1949). In United States v. Kaadt, 171 F. 2d 600, 603-604 (7 Cir. 1948), the court said: ". . . [A] consensus of medical opinion is a question of fact . . . and . . . a conflict of medical opinion concerning the effectiveness of a drug also presents a question of fact."

The test of whether a finding of fact is "clearly erroneous" within the meaning of Rule 52(a) is definitively set forth in United States v. Gypsum Co., 333 U. S. 394, 395 (1948). The Supreme Court said: "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has

been committed." In the case at bar the trial judge made a choice between conflicting medical opinions. We cannot say that this constituted error, for there was evidentiary basis for his resolution of the conflict. Colusa Remedy Co. v. United States, *supra*. See also Harry Alter Co. v. Chrysler Corp., 285 F. 2d 903 (7 Cir. 1960), ". . . [A] choice between two permissible views of the weight of evidence is not 'clearly erroneous'", United States v. Yellow Cab Co., 338 U. S. 338, 342 (1949). Applying these standards, we are compelled to the conclusion that the findings of fact made in the court below are not clearly erroneous, and accordingly, they must be affirmed.

Moreover, we think that the district court was correct in its application of the pertinent legal standards as to what constitutes "false or misleading" labeling and in its conclusions of law on this question. The court properly ignored the fact that the capsules might have a beneficial effect on some persons as a result of the vitamin content. In United States v. One Device, Etc., 160 F. 2d 194, 200 (10 Cir. 1947), the court said: "The objection is not to the use of this . . . [article] or that it does not have a useful place in the art of healing. The vice is in the way and manner in which it is represented and the claims which are made for it in these circulars . . ."[14] Although it is possible, as the trial court found, that the vitamins in Jenasol capsules may indeed be effective in the treatment of some of the ailments mentioned in the literature, the clear and unmistakable tenor of the leaflets is that royal jelly will itself relieve the human illnesses and ailments enumerated therein. As was said by trial court: "It is

[14] "It must be remembered that a representation may be 'misleading' from the very fact of overemphasis and exaggeration, even though the product in question may be helpful, and in some circumstances useful, though not really indispensable to good health." V. E. Irons, Inc. v. United States, 244 F. 2d 34, 43 (1 Cir. 1957), certiorari denied, 354 U. S. 923 (1957).

upon the royal jelly that sufferers from the conditions stated are induced by the literature to pin their hopes and fasten their expectations of alleviation and restoration." 204 F. Supp. 915 at p. 917. In V. E. Irons, Inc. v. United States, 244 F. 2d 34, 39-40 (1 Cir. 1957), certiorari denied, 354 U. S. 923 (1957), the court stated: "In determining whether such labeling contained 'false or misleading' statements, we must be careful not to read the literature with the eyes either of experts in nutrition or of overly skeptical buyers. What is pertinent is the effect the claims would have on those to whom they are addressed, namely, prospective purchasers and actual customers . . . who cannot be presumed to have special expertness or to be unduly cautious, but who are more likely than not to be persons who are pathetically eager to find some simple cure-all for the diseases with which they are afflicted or who are susceptible to luridly painted scare literature as to the prospect of being disease-ridden unless they consistently partake of the vaunted drug product. This approach has been authoritatively approved."

It is true, as is pointed out in Jenasol's brief, that one of the leaflets, the one bearing the title "Miracle Bullets", contains as a disclaimer statement the following: "We make no claims for ROYAL JELLY. We have merely accumulated reports that have been made as a result of experimentation and research by Doctors, Scientists, and Nutritionists in many parts of the world. Many of these reports have been published in reputable publications, in official Journals, and before the International Congress of Doctors and Biogeneticists." Nonetheless, this technical disclaimer cannot cure the leaflet of its deceptive and misleading character as a whole. The disclaimer is located on the third page of the four page circular, in small type, and at the bottom of a column. Every other column or item in this newspaper format leaflet bears a headline in heavy, large type, whereas this disclaimer is simply issued as a

final inconspicuous paragraph in a "news item" pointing out the research done on royal jelly. The single paragraph does not caution the reader of the leaflet that the representations made therein are, in fact, not representations at all, which is the alleged purpose of the disclaimer. The sweeping, remedial purposes of the Federal Food, Drug and Cosmetic Act, see United States v. Dotterwich, 320 U. S. 277 (1943), cannot be thwarted by a payment of mere lip service to the duty to fairly represent to potential customers the efficacy of a drug product.

We conclude that the district court's findings of fact that the labeling as a whole is false and misleading are not clearly erroneous, and that its conclusions of law that the drug is misbranded are correct.

Jenasol's final contention is that the district court committed error when it granted the injunctive relief prayed for in the amended libel.

As has been said at an earlier point in this opinion, the trial court filed an opinion on December 14, 1961, stating that a decree of condemnation would be issued. As of the date of that opinion, and throughout the trial that preceded it, the prayer for relief in the libel requested only that a decree of condemnation be issued. There was no specific prayer for injunctive relief. On December 18, 1961, Jenasol moved for a stay of entry of judgment and for clarification of findings of fact. On January 16, 1962, while that motion was pending, an order to show cause having issued, the United States moved to amend the libel to include a prayer for injunctive relief. Both motions were argued on January 22, 1962, and decision was reserved. On February 6, 1962, the District Court filed a second opinion, in which it stated it would grant the motion to amend the libel, deem the libel to be amended to include a prayer for injunction, and grant the injunction.

Thereafter, on February 21, 1962, the court entered a final decree, that appealed from, of condemnation and injunction.

The motion by the United States to amend its libel was expressly based on Rule 15(b), Fed. R. Civ. Proc., 28 U. S. C. This, in pertinent part, provides: "When issues raised by the pleadings are tried by express or implied consent of the parties, they shall be treated in all respects as if they had been raised in the pleadings. Such amendment of the pleadings as may be necessary to cause them to conform to the evidence and to raise these issues may be made upon motion of any party at any time, even after judgment; . . . [T]he court may allow the pleadings to be amended and shall do so freely when the presentation of the merits of the action will be subserved thereby and the objecting party fails to satisfy the court that the admission of such evidence would prejudice him. . . ." Whether this motion, nominally brought under Rule 15(b), was one that could have more properly been brought under Rule 15(a),[15] is a point we need not now determine, for under either rule the disposition of the issues presented lie within the discretion of the trial judge. See Caddy-Imler Creations, Inc. v. Caddy, 299 F. 2d 79 (9 Cir. 1962). This discretion, while quite broad, is not unlimited and cannot be exercised in such a manner as to result in substantial prejudice to a party. Ricciuti v. Voltare Tubes, Inc., 277 F. 2d 809 (2 Cir. 1960).

We think that in the case at bar the trial judge did not properly exercise his legal discretion in granting leave to

[15] Rule 15(a) provides in part: "A party may amend his pleading once as a matter of course at any time before a responsive pleading is served or, if no responsive pleading is permitted and the action has not been placed upon the trial calendar he may so amend it at any time within 20 days after it is served. Otherwise a party may amend his pleading only by leave of court, and leave shall be freely given when justice so requires."

amend the prayer for relief at such a late stage in the proceedings. Assuming *arguendo* that the court below had jurisdiction over the person of the claimant so as to have the power to grant injunctive *in personam* relief, an issue we need not and therefore do not decide,[16] we nonetheless think it unfair and substantially prejudicial to permit the injection of a new and different prayer for relief after trial at the very end of the case as was allowed here. But for the brief oral argument on the motion, Jenasol had no opportunity to raise and assert, through evidence or otherwise, equitable considerations by way of defense to an injunction or other possible mitigating factors. United States v. 184 Barrels Dried Whole Eggs, 53 F. Supp. 654 (E. D. Wis. 1943), is not to the contrary although the court there permitted an amendment for injunctive relief in a Federal Food, Drug and Cosmetic Act case. However, the amendment in the cited case was made at an early stage of the trial. This is a very different thing than the allowance of a far-reaching amendment after trial and at the terminal stage of district court proceedings as was permitted here.

Accordingly, the judgment of the District Court will be affirmed as to the decree of condemnation but will be reversed as to the injunctive relief granted.

A True Copy:

Teste:

Clerk of the United States Court of Appeals for the Third Circuit.

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[16] As we are able to decide this portion of the appeal on the issue of whether or not the trial judge abused his discretion in granting the amendment, we expressly do not resolve the interesting question of whether the claimant has made a general and unlimited appearance in the case and has thereby conferred *in personam* jurisdiction on the court, or whether such *in personam* jurisdiction has been conferred by consent or waiver.

JUDGMENT

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 14,035

UNITED STATES OF AMERICA

vs.

An Article of Drug Consisting of 47 Bottles, More or Less, Each Containing 30 Capsules of an Article Labeled in Part "* * * Jenasol RJ Formula '60' * * *"

MARVIN SCHERR, doing business as THE JENASOL COMPANY, Appellant

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE ..... DISTRICT OF NEW JERSEY

Present: BIGGS, *Chief Judge*, and KALODNER and FORMAN, *Circuit Judges*.

This cause came on to be heard on the record from the United States District Court for the ..... District of New Jersey and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court in this case be, and the same is hereby affirmed as to the decree of condemnation and is reversed as to the injunctive relief granted.

Attest:

IDA O. CRESKOFF
Clerk

July 16, 1963

ORDER

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 14,035

UNITED STATES OF AMERICA,

v.

An article of drug consisting of 47 bottles, more or less, each containing 30 capsules of an article labeled in part "* * * JENASOL B.I. FORMULA '60' * * * * *".

MARVIN SCHERR, Doing business as the JENASOL COMPANY,
Appellant

Present: BIGGS, Chief Judge; and KALODNER and FORMAN, Circuit Judges.

Upon consideration of the motion by appellant;

It is ORDERED that issuance of the mandate in the above case be, and it is hereby, stayed until October 14, 1963.

By the Court,

BIGGS
Chief Judge

August 29, 1963

APPENDIX B

STATUTES

The Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, et seq.) provides in pertinent part:

Sec. 201 (m):

The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article [21 U. S. C. 321 (m)].

Sec. 201 (n):

If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual [21 U. S. C. 321 (n)].

Sec. 304:

(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in inter-

state commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . . [21 U. S. C. 334].

Sec. 502 (a):

A drug or device shall be deemed to be misbranded—

If its labeling is false or misleading in any particular [21 U. S. C. 352 (a)].